

232989US0

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :
Claude DUBIEF, et al. : EXAMINER: WILLIAMS, LEONARD
SERIAL NO: 10/717,626 :
FILED: NOVEMBER 21, 2003 : GROUP ART UNIT: 1617
FOR: PROCESS FOR THE PREPARATION OF A
CATIONIC NANOEMULSION, AND COSMETIC
COMPOSITION

DECLARATION UNDER 37 C.F.R. 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VA 22313

SIR:

I, Géraldine FACK, hereby declare:

1. I am a named inventor on the above-identified patent application.
2. The following observations and experiments were carried out by me or under my direct supervision and control.
3. The following composition was prepared:

Ingredient	Amount
Isopropyl Myristate (Cognis)	10 g
PEG 35 Castor Oil (Cremophor EL -- BASF)	7.5 g
PEG 7.5 Hydrogenated Castor Oil (Arlacel 989 -- Uniquema)	2.5 g
Behentrimonium Chloride	2 g
Water	Qsp to 100 g

This composition was prepared twice. Once using the invention processes. The other time using a comparative process.

4. The composition prepared according to the invention processes was prepared as follows (“Invention Composition”):

Phase A

Isopropyl myristate (fatty phase) was mixed with non-ionic surfactants (PEG 35 Castor Oil and PEG 7 hydrogenated castor oil). The mixture was heated to 70°C. Then, 75% of the water was added. This mixture was progressively heated to 70°C, under moderate agitation. At 70°C, the mixture was mixed for 30 minutes.

Phase B

In a separate container, cationic surfactant (behentrimonium chloride) was solubilized in the remaining water with mixing at 70°C.

Phase B was introduced into Phase A with mixing at 70°C. The mixture was then allowed to cool to ambient temperature. (Additional water can be added at this point).

5. The composition prepared according to the comparative process was prepared as follows (“Comparative Composition”):

Isopropyl myristate (fatty phase) was mixed with non-ionic surfactants (PEG 35 Castor Oil and PEG 7 hydrogenated castor oil) and cationic surfactant (behentrimonium chloride). The mixture was heated to 70°C. Then, the water was added. This mixture was progressively heated to 70°C, under moderate agitation. At 70°C, the mixture was mixed for 30 minutes. The mixture was then allowed to cool to ambient temperature. (Additional water can be added at this point).

6. The appearance and stability of these two compositions was compared. More specifically, the number average particle size and turbidity of these compositions were determined according to the description in the present application. (See, page 6).

7. The Invention Composition was a transparent nanoemulsion. Generally speaking, transparency corresponds to the concept of a nanoemulsion, indicating that the compositions contain oil globules of homogeneous size, not heterogeneous size. The Invention Composition also had a number average particle size of 60 nm and a turbidity of 353 NTU. Moreover, after 10 days, turbidity was measured, and the turbidity was not substantially different (360 NTU). Finally, no composition instability (phase separation) was noticed at ambient temperature.

8. The comparative composition was opaque, with a number average particle size of 102 nm and a turbidity of 715 NTU. After 10 days, turbidity was measured, and the turbidity was substantially increased (815 NTU). Instability of the composition was noticed at ambient temperature.

9. It was surprising and unexpected that using the invention composition and the comparative composition had vastly different properties given that these two compositions were identical except for their manner of preparation.

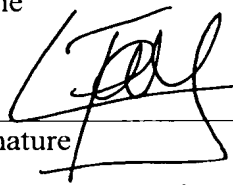
10. The improved properties of the Invention Composition are representative of the present invention. That is, I would expect nanoemulsions made by a process comprising (a) mixing, with agitation, at least one fatty compound and at least one non-ionic surfactant at a temperature T_m above the melting point of the at least one fatty compound and the at least one non-ionic surfactant under normal atmospheric pressure, wherein the at least one non-ionic surfactant and the at least one fatty compound are present in amounts suitable to form an oil-in-water emulsion with water; (b) adding water, with agitation, to form an oil-in-water nanoemulsion, and (c) adding at least one cationic surfactant to the nanoemulsion, to possess

improved properties like those of the Invention Composition in this declaration. I have no reason to expect otherwise.

11. The fact that the nanoemulsions produced by the methods of the present invention are transparent is commercially significant. Transparency is a desirable characteristic in certain types of cosmetic products: it indicates to consumers the product is pure and hygienic. Opaqueness, on the other hand, can be an undesirable characteristic in such products.

12. The undersigned petitioner declares further that all statements made herein of her own knowledge are true and that all statements made on information and belief are believe to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

13. Further deponent sayeth not.

Géraldine FACK
Name

Signature
7105108.
Date